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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/391,783

Applicant(s)

Baldwin et al.

Examiner
Grace Hsu, Ph.D.

Group Art Unit
1627



☒ Responsive to communication(s) filed on Jul 24, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 4-7 and 38 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4-7 and 38 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The Amendment Under 37 C.F.R. § 1.121(a) and Response to Restriction Requirement Under 37 C.F.R. 1.143 received on July 24, 2000 were entered as Paper No. 7.

Status of Claims

2. Claims 4-14 and 38 are pending, claim 38 was added in the July 24, 2000 Amendment and claims 1-3 and 15-37 were canceled by the September 8, 1999 Preliminary Amendment.
3. Claims 4-7 and 38 are under examination in the current application.

Election/Restriction

4. Applicants' election of: [1] Group I, claims 4-7, without traverse, drawn to a compound of Formula (II); and [2] the species of Formula (II), wherein each of the functional group substituent groups, R^1 , R^2 , R^4 - R^7 , R^{14} and R^{15} attached to the core ring, are defined by chemical structure pictorial representation at the bottom of page 2 of the July 24, 2000 Amendment is acknowledged.
5. Claims 8-14 are withdrawn from further consideration by the Examiner under 37 CFR 1.142(b), as being drawn to a non-elected inventions of Groups II-VI, the requirement not traversed in Paper No. 7.
6. The elected species of Formula (II), as defined by variable and chemical structure representation on page 2 of applicants' July 24, 2000 Amendment and claim 38, has been found free of the prior art to date. The search has been expanded to encompass the remaining non-

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elected species, as provided for under current Markush examination practice at the discretion of the Examiner.

Claim Objections

7. Claims 5-7 are objected to for typographical errors. For the sake of clarity, applicants are requested to amend claims 5-7 to insert a comma after the term "A compound of claim 4" preceding the term "wherein."

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4-7 and 38 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 4-7 and 38 are vague and indefinite for the recitation of the following terms: [1] "lower alkyl", "hetero lower alky"l, "lower alkoxy", "mono or di lower alkyl"; "di lower alkyl"; "lower amido", "S- lower alkyl", "lower alkyl"; "lower alkyl sulfamoyl", "aryl lower alkyl", etc. It is unclear what each recitation of the term "lower" refers to in association with the various functional groups recited in the claims, as the metes and bounds of the aforementioned claim cannot be determined as the specification, claims and art do not recognize what that terms means (e.g., i.e., does it mean a "___ group of 1-6 carbons?). Applicants are requested to point to

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where in the specification that term is defined and to amend the claims to define the specific number of carbon atoms that constitutes the term "lower alkyl" for each reference to that term among all the recited functional groups defined in the aforementioned claims.;

[2] "substituted" or "optionally substituted with" lower alkyl, aryl, heteroaryl, etc.; It is unclear what each recitation of the term "substituted" or "optionally substituted with" refers to in association with the various functional groups recited in the claims, as the metes and bounds of the aforementioned claim cannot be determined as the specification, claims and art do not recognize what the aforementioned functional groups are "substituted" or "optionally substituted" with? Applicants are requested to point to where in the specification for support is found for what substituent groups are associated with each functional group defined in the claims and to amend the claims accordingly.;

[3] in the definition of R1: "OCH₂-4-**Phe**-C(O)NH(CH₂)₁₋₆R¹⁷", it is unclear what the term "Phe" refers to, as the metes and bounds of the aforementioned claim cannot be determined as the specification, claims and art do not recognize what such a terms mean as the claims what that abbreviated term is. Applicants are requested to: [a] point to where in the specification that term is defined; [b] to amend the claims to define what the specific functional group moiety "phe" represents as is conventionally known in the chemical arts (i.e., phenyl or C₆H₄); and [c] review the claims to correct for the recitation of the term "phe" as it may be recited in the definition of other functional group substituents.;

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[4] the groups "R⁴ and R⁵", "R⁶ and R⁷", etc. "are taken together", it is unclear how each of the independently discrete functional group moieties defined in the claims, as the variables "R⁴", "R⁵", "R⁶", "R⁷", etc. are ultimately "taken together" or linked to form the bridging functional group moieties defined in the claims after the term "taken together," as the metes and bounds of the aforementioned claim cannot be determined as the specification, claims and art do not recognize what such a term "taken together" means as the specification, claims and art do not recognize how the aforementioned each of the aforementioned independent functional groups are "taken together" to form those bridging moieties?. Applicants are requested to point to where in the specification an explanation is provided for how each of the independently variables are taken together to form the linking bridge units.

11. Claims 4-7 and 38 recites the following limitations: "the substituents", "the heteroatom", etc. There is insufficient antecedent basis for those limitations in each of those claims. Applicants are requested to check each of the aforementioned claims and to amend the claims accordingly.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Jennings (J. Chem. Soc. Perkin Trans., 1984, page 1733-1738).

The claimed invention is directed to a substituted dihydrobenzopyran compound of formula (II), wherein the following functional group variables are substituted on different positions of the bicyclic fused ring core, wherein the pyran portion of that core is substituted with an oxygen atom at the 1-position, "R⁴" and "R⁵" at the 2-position, and "R⁶" and "R⁷" at the 4-position, while the benzo portion of the ring core at any one of positions 5-8 may be substituted with "R¹" and "R²", wherein each of the aforementioned variables are respectively defined in the claims and/or instant specification.

Jennings discloses: [1] a dihydrobenzopyran compounds and corresponding derivatives that anticipate the compounds of the claimed invention; [2] wherein the aforementioned compounds have functional group substituents that are anticipated and correspond to the R¹, R², R⁴-R⁷ functional group substituents on the dihydrobenzopyran ring core of the claimed invention; and [3] for example compound species that anticipate the claimed compounds are substituted with following corresponding groups, wherein: [a] R¹ is either hydroxy or methoxy and or R² is hydrogen (also viceversa) ; R⁴ = R⁵ = methyl, R⁶ and R⁷ taken together = "C=O"(see, page 1735, col. 1, Compounds 24 and 25).

Therefore, Jennings anticipates the claimed invention.

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14. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by EP Patent Application No.: 0 415 566 A1, Publication Date: March 6, 1991.

EP Appln. No. 0 415 566 A1 discloses: [1] a dihydrobenzopyran compounds and corresponding derivatives that anticipate the compounds of the claimed invention; [2] wherein the aforementioned compounds have functional group substituents that are anticipated and correspond to the R^1 , R^2 , R^4 - R^7 functional group substituents on the dihydrobenzopyran ring core of the claimed invention; and [3] example compound species that anticipate the claimed compounds are substituted with the following groups, wherein: [a] Y is O, R1 and R2 are independently hydrogen, lower alkyl, phenyl or substituted phenyl (which corresponds to R4 and R5 of the claimed invention), R3 is hydrogen, B is a C=O (which corresponds to R6 and R7 of the claimed invention), R6 is a hydrogen or lower alkyl (which corresponds to R2 of the claimed invention) and " R^7 OCO-A-Z", wherein Z is oxygen, A is a straight or branched hydrocarbon radical having one to five carbon atoms, and R7 (R7 recited therein is distinguished from R7 of the claimed invention; note that the group " R^7 OCO-A-Z" corresponds to R1 of the claimed invention, wherein R1 is O-(CH₂)CO₂H is hydrogen.

Therefore, EP Appln. No. 0 415 566 A1 anticipates the claimed invention.

15. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,268,386 (herein referred to as "the U.S. '386 Patent", Issued: December 7, 1983, Filed July 26, 1990.

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The U.S. '386 Patent discloses: [1] a dihydrobenzopyran compounds and corresponding derivatives that anticipate the compounds of the claimed invention; [2] wherein the aforementioned compounds have functional group substituents that are anticipated and correspond to the R^1 , R^2 , R^4 - R^7 functional group substituents on the dihydrobenzopyran ring core of the claimed invention; and [3] example compound species that anticipate the claimed compounds are substituted with the following groups, wherein: [a] Y is O, R_1 and R_2 are independently hydrogen, lower alkyl, phenyl or substituted phenyl (which corresponds to R_4 and R_5 of the claimed invention), R_3 is hydrogen, B is a C=O (which corresponds to R_6 and R_7 of the claimed invention), R_6 is is a hydrogen or lower alkyl (which corresponds to R_2 of the claimed invention) and " R^7 OCO-A-Z", wherein Z is oxygen, A is a straight or branched hydrocarbon radical having one to five carbon atoms, and R_7 (R_7 recited therein is distinguished from R_7 of the claimed invention; note that the group " R^7 OCO-A-Z" corresponds to R_1 of the claimed invention, wherein R_1 is O-(CH₂)CO₂H is hydrogen.

Therefore, the U.S. '386 Patent anticipates the claimed invention.

Status of Claims

16. No claims are allowed in the above-identified application.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The

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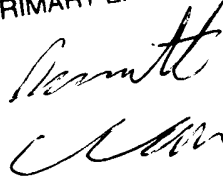
Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 6:00 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Keith Macmillan, may be reached at (703) 308-4614. The fax number assigned to Group 1627 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1627 receptionist whose telephone number is (703) 308-0196.

Grace C. Hsu, Ph.D., J.D.

October 6, 2000

BENNETT CELSA
PRIMARY EXAMINER

Handwritten signature of Bennett Celsa, consisting of a stylized 'B' followed by 'Celsa'.